

REMARKS

Claims 3 – 8, 10, 12, 13, 15, and 19 are currently pending in the application. Claims 4, 6, 12, 15, and 19 have been amended. Applicants submit that no new matter has been introduced into the application by these amendments.

Telephonic Interview

The Examiner is thanked for granting telephonic interviews with the Applicants' representative, Robert Ballarini, on April 5, 2007 and August 21, 2007. During the interviews the above amendments as well as the Crane reference were discussed.

Claim Rejections - 35 USC § 112

Claims 3 – 8, 10, 12, 13, 15, and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite because. The Examiner indicated that the phrase "surgically implantable" in claims 12, 15 and 19 is unclear; that in claim 4 the phrase "further comprising PAEK (poly-aryl-ether ketone)" is unclear; and in claim 6 "the fibers are enveloped by as matrix material" is unclear.

Claims 12, 15, and 19 have been amended to include the term "biocompatible" which was agreed upon by the Examiner during the telephone interview on April 5,

2007, as to sufficiently clarify the term "surgically implantable." Support for the term biocompatible is found in the specification on page 8, lines 7 - 8, and lines 30 - 32. Support for the term "surgically implantable" is found in the specification on page 7, lines 8 - 14: "On the one hand, this invention involves a composite consisting of polymer or ceramic material with a content of integrated reinforcing elements in the form of fibers or fibrous parts, for the manufacture of components exposed to tensile, bending, shear, compressive and/or torsional stress for use in implants, e.g., osteosynthesis plates, endoprostheses, screw coupling elements, in surgical instruments, as already enumerated above." The amendment to claims 4, 6, 12, 15 and 19 therefore obviate the rejection under § 112. Based on the amendments above, the withdrawal of the §112 rejection is respectfully requested.

Claim Rejections - 35 USC § 102

Claims 3, 5 – 8, 10, 12, 13, 15, and 19 were rejected in the Action under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,255,478 to Crane. Applicants respectfully traverse the rejection of these claims and respectfully submit that these claims are patentable over the art of record for at least the reasons set forth below.

As discussed and agreed upon during the teleconference with Applicants' representative, the Examiner indicated that amendments to claims 12, 15 and 19 obviate the rejection in view of the Crane reference.

Applicants: Magerl et al.
Application No.: 09/701,104

The invention as currently claimed in independent claim 12 is a surgically implantable biocompatible component including a composite of polymer or ceramic material and X-ray absorbing reinforcing fibers distributed throughout the composite. An orientation of the X-ray absorbing reinforcing fibers is tailored to a shape and application of the surgically implantable biocompatible component in a defined manner to provide X-ray visibility control for the surgically implantable biocompatible component. The component also including carbon fibers. A total fiber percentage in the composite remains constant over a length or width of the biocompatible component, which changes a ratio of carbon fibers to X-ray absorbing fibers.

The invention as currently claimed in independent claim 15 is a surgically implantable biocompatible component in the form of a strip or plate assembly part. The surgically implantable biocompatible component includes a composite of polymer or ceramic material and X-ray absorbing reinforcing fibers distributed throughout the composite. An orientation of the X-ray absorbing reinforcing fibers is tailored to a shape and application of the surgically implantable biocompatible component in a defined manner to provide X-ray visibility control for the component. A concentration of fibers is present in an area having one or more

recesses or holes in the biocompatible component. The percentage of the X-ray absorbing fibers is reduced in the area having one or more recesses or holes.

Furthermore, the invention as claimed in independent claim 19 is a surgically implantable biocompatible component having a composite of polymer or ceramic material and reinforcing fibers. At least some of the reinforcing fibers are X-ray absorbing reinforcing fibers distributed throughout the composite. An orientation of the X-ray absorbing reinforcing fibers is tailored to a shape and application of the surgically implantable biocompatible component to provide X-ray visibility control for the biocompatible component. A concentration of the X-ray absorbing fibers is varied in different areas of the biocompatible component.

In contrast, Crane neither discloses nor suggests an **X-ray absorbing reinforcing fiber**. Crane states in column 2, lines 20 - 26: "Various fiber-reinforced tapes suitable for fabricating composites or laminates can be used in the practice of the present invention. Examples of materials that can be utilized as reinforcement include glass, aluminum oxide, carbon and graphite fibers as well as organic fibers generally. However, it should be understood that the invention is **not applicable to** tapes that are reinforced with **boron fibers**." Thus, the X-ray absorbing fibers of Crane, namely boron fibers, are not reinforcing fibers. Instead,

glass, aluminum oxide, carbon and graphite fibers (not X-ray absorbing) are reinforcing fibers.

Further, Crane neither discloses nor suggests an orientation of X-ray absorbing reinforcing fibers tailored to a shape and application of a surgically implantable biocompatible component, and a constant total fiber percentage in the composite which changes a ratio of carbon fibers to X-ray absorbing fibers. More specifically, Crane discloses a composite structure comprised of plies of fiber-reinforced tape segments in which the fibers are embedded in a resin matrix so as to be parallel to the edges of the tape. See column 2, lines 62 – 64 of Crane. As illustrated in Fig. 1, a boron fiber (14) is positioned along and between the abutting edges of the tape segments. Column 3, lines 13 – 14. The tape segments (18) of each ply are arranged in a 45°, - 45° pattern and, since the boron fibers are laid along edges of the tape segments, they are likewise arranged in a 45°, - 45° pattern. Column 3, lines 29 – 37. Importantly, the arrangement of boron fibers is such that no single boron fiber is positioned vertically over another boron fiber. Column 3, lines 38 – 40. In other words, the structure of Crane requires a very specific configuration, and nowhere does Crane disclose or suggest an orientation of **X-ray absorbing reinforcing fibers** *tailored to* a shape and application of a surgically implantable biocompatible component. Similarly, Crane neither discloses nor suggests a constant total fiber percentage in the composite which changes a ratio of

carbon fibers to X-ray absorbing fibers. Thus, Crane fails to recite each and every feature of Applicants' claimed invention.

It is because Applicants' invention comprises an orientation of X-ray absorbing reinforcing fibers tailored to a shape and application of a surgically implantable component, and a constant total fiber percentage in the composite which changes a ratio of carbon fibers to X-ray absorbing fibers that the following advantages are achieved. Tailoring the orientation of the X-ray absorbing reinforcing fibers makes it possible to graduate the visibility of the surgically implantable component, i.e., of an implant. See page 5, lines 1 - 11 of the specification. Depending on the segments of an implant where a stronger, weaker, or even no X-ray visibility is desired, it is possible to control the application and used quantity of fibers made out of X-ray opaque materials. (Specification, page 5, lines 7 - 13) Hence, the ability to concentrate or accumulate these fibers is of particular importance. Because the total fiber percentage in the composite remains constant (which changes a ratio of carbon fibers to X-ray absorbing fibers), the visibility can be deliberately controlled for an optimal X-ray diagnostics, without impairing the strength values of the surgically implantable component. (Specification, page 5, line 31 – page 6, line 2)

Applicants: Magerl et al.
Application No.: 09/701,104

Thus, because independent claims 12, 15 and 19 currently recite features that are neither disclosed nor suggested by Crane, Applicants respectfully submit that claims 12, 15 and 19 should be allowed.

Applicants further respectfully submit that because claims 3 – 8, 10, and 13 are dependent upon allowable claim 19, claims 3 – 8, 10, and 13 should also be allowed at least as dependent upon an allowable base claim. Reconsideration of these claims is respectfully requested.

Conclusion

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is encouraged to contact the undersigned by telephone at the Examiner's convenience.

Applicants: Magerl et al.
Application No.: 09/701,104

In view of the foregoing amendments and Remarks, Applicants respectfully submit that the present application, including claims 3 – 8, 10, 12, 13, 15, and 19, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

Magerl et al.

By Robert J. Ballarini
Robert J. Ballarini
Registration No. 48,684

Volpe and Koenig, P.C.
United Plaza, Suite 1600
30 South 17th Street
Philadelphia, PA 19103-4009
Telephone: (215) 568-6400
Facsimile: (215) 568-6499

RJB/srs